

Charles M. Lizza  
William C. Baton  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102-5426  
(973) 286-6700

*Attorneys for Plaintiffs  
Helsinn Healthcare S.A. and  
Roche Palo Alto LLC*

*Of Counsel:*

Joseph M. O'Malley, Jr.  
Eric W. Dittmann  
Young J. Park  
Isaac S. Ashkenazi  
Gary Ji  
Angela C. Ni  
Dana Weir  
PAUL HASTINGS LLP  
75 East 55th Street  
New York, NY 10022  
(212) 318-6000

*Attorneys for Plaintiff  
Helsinn Healthcare S.A.*

Mark E. Waddell  
LOEB & LOEB LLP  
345 Park Avenue  
New York, NY 10154  
(212) 407-4127

*Attorneys for Plaintiff  
Roche Palo Alto LLC*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A. and  
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

ACTAVIS LLC,

Defendant.

**Civil Action No.** \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC  
("Roche") (collectively, "Plaintiffs"), for their Complaint against Actavis LLC ("Actavis")  
hereby allege as follows:

### **THE PARTIES**

1. Helsinn is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

2. Roche is a company, organized and existing under the laws of the State of Delaware, having a principal place of business at One DNA Way, South San Francisco, California 94080-4990.

3. Upon information and belief, Defendant Actavis is an entity organized and existing under the laws of the State of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Defendant Actavis manufactures, markets, and/or sells various generic drug products for sale and use in the State of New Jersey and throughout the United States.

### **NATURE OF THE ACTION**

4. This is a civil action concerning the infringement of United States Patent No. 7,947,724 (“the ’724 patent”) and United States Patent No. 9,066,980 (“the ’980 patent”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

### **JURISDICTION AND VENUE**

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

6. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court’s jurisdiction.

7. Venue is proper in this Court as to Defendant Actavis pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

8. This Court has personal jurisdiction over Defendant Actavis because, *inter alia*, Defendant Actavis has committed, aided, abetted, contributed to, and/or participated in an act of patent infringement that has led to foreseeable harm and injury to Plaintiffs. This Court has personal jurisdiction over Defendant Actavis for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Actavis because, *inter alia*, it: (1) has its principal place of business in New Jersey; (2) engages in persistent conduct within New Jersey, including, upon information and belief, the preparation and submission of NDA No. 208522; (3) has purposely availed itself of the privilege of doing business in this Judicial District; (4) maintains extensive systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to New Jersey residents; (5) has registered with the New Jersey Department of Health as a wholesale drug manufacturer; and (6) has sent the Paragraph IV Notice, including a detailed statement of the factual and legal bases for its belief that the challenged patents are invalid or not infringed by Actavis's proposed generic product, into New Jersey.

#### **THE PATENTS-IN-SUIT**

10. On May 24, 2011, the '724 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '724 patent is attached as Exhibit A.

11. On June 30, 2015, the '980 patent, titled "Liquid Pharmaceutical Formulations of Palonosetron," was duly and legally issued to Plaintiffs as assignees. A copy of the '980 patent is attached as Exhibit B.

12. Pursuant to 21 U.S.C. § 355(b)(1), the '724 patent and the '980 patent are listed in the United States Food and Drug Administration ("FDA") publication titled, "Approved

Drug Products with Therapeutic Equivalence Evaluations” (also known as the “Orange Book”) as covering Helsinn’s Aloxi<sup>®</sup> brand palonosetron hydrochloride intravenous solutions.

**ACTS GIVING RISE TO THIS ACTION**

**COUNT I – INFRINGEMENT OF THE ’724 PATENT**

13. Plaintiffs reallege paragraphs 1-12 as if fully set forth herein.

14. Upon information and belief, Defendant Actavis submitted NDA No. 208522 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208522 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Plaintiffs’ Orange Book-listed patents that have the same expiration date as the ’724 patent. NDA No. 208522 specifically seeks FDA approval to market a generic version of Helsinn’s Aloxi<sup>®</sup> brand palonosetron hydrochloride intravenous solutions prior to the expiration of the ’724 patent.

15. Upon information and belief, NDA No. 208522 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the ’724 patent are invalid. Defendant Actavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

16. Defendant Actavis’s submission to the FDA of NDA No. 208522, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the ’724 patent under 35 U.S.C. § 271(e)(2)(A).

17. Defendant Actavis’s active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 208522 and the § 505(b)(2)(A)(iv) certification constitutes infringement of the ’724 patent under 35 U.S.C. § 271(e)(2)(A).

18. Plaintiffs are entitled to a declaration that, if Defendant Actavis commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Defendant Actavis will infringe the '724 patent under 35 U.S.C. § 271(a), (b), and/or (c).

19. Plaintiffs will be irreparably harmed by Defendant Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

## **COUNT II - INFRINGEMENT OF THE '980 PATENT**

20. Plaintiffs reallege paragraphs 1-19 as if fully set forth herein.

21. Upon information and belief, Defendant Actavis submitted NDA No. 208522 to the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). NDA No. 208522 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic palonosetron hydrochloride intravenous solutions prior to the expiration of certain of Plaintiffs' Orange Book-listed patents that have the same expiration date as the '980 patent. NDA No. 208522 specifically seeks FDA approval to market a generic version of Helsinn's Aloxi<sup>®</sup> brand palonosetron hydrochloride intravenous solutions prior to the expiration of the '980 patent.

22. Upon information and belief, NDA No. 208522 includes a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act that the claims of the '980 patent are invalid. Defendant Actavis notified Plaintiffs of its certification and provided a detailed statement of the alleged basis for the certification.

23. Defendant Actavis's submission to the FDA of NDA No. 208522, including the § 505(b)(2)(A)(iv) allegations, constitutes infringement of the '980 patent under 35 U.S.C. § 271(e)(2)(A).

24. Defendant Actavis's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of NDA No. 208522 and the § 505(b)(2)(A)(iv) certification constitutes infringement of the '980 patent under 35 U.S.C. § 271(e)(2)(A).

25. Plaintiffs are entitled to a declaration that, if Defendant Actavis commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Defendant Actavis will infringe the '980 patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. Plaintiffs will be irreparably harmed by Defendant Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs request that:

A. A Judgment be entered declaring that Defendant Actavis has infringed the '724 and '980 patents by submitting NDA No. 208522;

B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of NDA No. 208522 be a date that is not earlier than the expiration dates of the '724 and '980 patents, or any later expiration of exclusivity for any of those patents to which Plaintiffs are or become entitled;

C. An Order be issued that Defendant Actavis, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing the proposed generic versions of Helsinn's Aloxi<sup>®</sup> brand products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '724 and '980 patents, prior to the expiration of any of those patents, including any extensions to which Plaintiffs are or become entitled;

D. Plaintiffs be awarded attorneys' fees pursuant to 35 U.S.C. § 285;

E. Plaintiffs be awarded their costs and expenses in this action; and

F. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: March 24, 2016

Respectfully submitted,

*Of Counsel:*

Joseph M. O'Malley, Jr.  
Eric W. Dittmann  
Young J. Park  
Isaac S. Ashkenazi  
Gary Ji  
Angela C. Ni  
Dana Weir  
PAUL HASTINGS LLP  
75 East 55th Street  
New York, NY 10022  
(212) 318-6000  
josephomalley@paulhastings.com  
ericdittmann@paulhastings.com  
youngpark@paulhastings.com  
isaacashkenazi@paulhastings.com

By: s/ Charles M. Lizza

Charles M. Lizza  
William C. Baton  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102-5426  
(973) 286-6700  
clizza@saule.com  
wbaton@saule.com

*Attorneys for Plaintiffs  
Helsinn Healthcare S.A. and  
Roche Palo Alto LLC*

garyji@paulhastings.com  
angelani@paulhastings.com  
danaweir@paulhastings.com

*Attorneys for Plaintiff  
Helsinn Healthcare S.A.*

Mark E. Waddell  
LOEB & LOEB LLP  
345 Park Avenue  
New York, NY 10154  
(212) 407-4127  
mwaddell@loeb.com

*Attorneys for Plaintiff  
Roche Palo Alto LLC*



**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Helsinn Healthcare S.A., et al. v. Dr. Reddy Laboratories, Ltd., et al.*, Civil Action No. 11-3962 (MLC)(DEA) (D.N.J. July 8, 2011) (Consolidated), *Helsinn Healthcare, S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 12-2867 (MLC)(DEA) (D.N.J. May 11, 2012), *Helsinn Healthcare, S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 14-4274 (MLC)(DEA) (D.N.J. July 7, 2014), *Helsinn Healthcare, S.A., et al. v. Hospira, Inc., et al.*, Civil Action No. 15-2077 (MLC)(DEA) (D.N.J. Mar. 23, 2015), *Helsinn Healthcare, S.A., et al. v. Fresenius Kabi USA, LLC, et al.*, Civil Action No. 15-7015 (MLC)(DEA) (D.N.J. Sept. 22, 2015); *Helsinn Healthcare, S.A., et al. v. Fresenius Kabi USA, LLC, et al.*, Civil Action No. 15-7378 (MLC)(DEA) (D.N.J. Oct. 8, 2015), *Helsinn Healthcare S.A., et al. v. Qilu Pharmaceutical Co., Ltd., et al.*, Civil Action No. 15-8132 (MLC)(DEA) (D.N.J. Oct. 17, 2015), *Helsinn Healthcare S.A., et al. v. Dr. Reddy Laboratories, Ltd., et al.*, Civil Action No. 15-8662 (MLC)(DEA) (D.N.J. Dec. 15, 2015), *Helsinn Healthcare, S.A., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 15-8663 (MLC)(DEA) (D.N.J. Dec. 15, 2015), *Helsinn Healthcare, S.A., et al. v. Sagent Pharmaceuticals, Inc., et al.*, Civil Action No. 16-173 (MLC)(DEA), *Helsinn Healthcare, S.A., et al. v. Sagent Pharmaceuticals, Inc.*, Civil Action No. 16-681 (MLC)(DEA), *Helsinn Healthcare, S.A., et al. v. Hospira, Inc.*, Civil Action No. 15-264 (GMS) (D. Del. Mar. 25, 2015), and *Helsinn Healthcare, S.A., et al. v. Exela Pharma Sciences LLC, et al.*, Civil Action No. 14-1444 (GMS) (D. Del. Dec. 1, 2014) (currently stayed) are related to the matter in controversy because the matter in controversy involves the same plaintiffs and the same or related patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical products.

Dated: March 24, 2016

Respectfully submitted,

*Of Counsel:*

Joseph M. O'Malley, Jr.  
Eric W. Dittmann  
Young J. Park  
Isaac S. Ashkenazi  
Gary Ji  
Angela C. Ni  
Dana Weir  
PAUL HASTINGS LLP  
75 East 55th Street  
New York, NY 10022  
(212) 318-6000  
josephomalley@paulhastings.com  
ericdittmann@paulhastings.com  
youngpark@paulhastings.com  
isaacashkenazi@paulhastings.com  
garyji@paulhastings.com  
angelani@paulhastings.com  
danaweir@paulhastings.com

*Attorneys for Plaintiff  
Helsinn Healthcare S.A.*

Mark E. Waddell  
LOEB & LOEB LLP  
345 Park Avenue  
New York, NY 10154  
(212) 407-4127  
mwaddell@loeb.com

*Attorneys for Plaintiff  
Roche Palo Alto LLC*

By: s/ Charles M. Lizza

Charles M. Lizza  
William C. Baton  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102-5426  
(973) 286-6700  
clizza@saule.com  
wbaton@saule.com

*Attorneys for Plaintiffs  
Helsinn Healthcare S.A. and  
Roche Palo Alto LLC*